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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,026	06/08/2005	George Gallagher	78803.05001	8906
34661	7590	07/25/2007		
CHARLES N. QUINN FOX ROTHSCHILD LLP 2000 MARKET STREET, 10TH FLOOR PHILADELPHIA, PA 19103			EXAMINER DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	
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			07/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,026	<b>Applicant(s)</b> GALLAGHER, GEORGE	
	<b>Examiner</b> Leslie R. Deak	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7, 9-26 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 9-26 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/8/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the multiple inlets of claims 10-11 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-7, 9-13, 16, 21, 22, 24, 26, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al.

In the specification and figures, Wessman discloses the apparatus substantially as claimed by applicant. With regard to claims 1, 16, and 26, Wessman discloses a giving set cap 10 that provides fluid communication between vessel 20 and chamber 12. The cap comprises a delivery tube with a main channel 13 for fluid delivery and a subsidiary channel 14 for fluid delivery. The cap comprises inlet/outlet openings at the top of each channel that are spaced to allow sufficient mixing as claimed by applicant. Subsidiary channel 14 comprises an inlet 16 that is disclosed as being pierced by a needle.

Wessman fails to disclose that the subsidiary inlet 16 is adapted to receive a needleless syringe. However, Loo discloses a fluid connector 56 with an injection port or subsidiary inlet 20 with a male luer lock end 22 configured for access with a needleless syringe in order to prevent accidental needle sticks (see columns 1-2, FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention

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to add the needleless connector disclosed by Loo to the connector disclosed by Wessman in order to prevent accidental needle sticks, as taught by Loo.

With regard to claims 2-3, Wessman is silent as to the distance between the openings of the main and subsidiary channels. However, it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). In the instant case, it appears that the distance between the openings as disclosed and illustrated by Wessman provides sufficient distance for mixing as claimed by applicant, rendering the distance claimed by applicant an unpatentable improvement over the prior art device.

With regard to claims 5-7, 9, 12, 22, 24, and 33, Wessman illustrates connector means at 10 that attaches the cap to chamber 12, and tapered sharp or piercing ends of insertion portion or delivery tubing 11 that allow the cap to be inserted into container 20 (see FIGS 1-2). Main channel 13 extends through connector means at 10, terminating in an outlet.

With regard to claims 10-11, it has been held that the mere duplication of the parts of a device disclosed by the prior art has no patentable significance unless a new and unexpected result is produced. See MPEP 2144.04(VI)(B). In the instant case, applicant fails to disclose a new and unexpected result from the multiple inlets, rendering the claimed inlets unpatentable over the prior art.

With regard to claims 13, 21, subsidiary channel 14 inlet (generally at 15) is located within the periphery of the connecting means, with a channel extending to the side of the connector.

4. Claims 14-15, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, further in view of US 3,662,752 to Yokoyama.

In the specification and figures, Wessman and Loo disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a detachable vent cap over the subsidiary inlet. Yokoyama discloses an infusion device with a needle 7 comprising a medicament passage from one chamber to another comprising a subsidiary inlet 17. Attached to the inlet 17 is a removable cap 29 with a filter 30 therein to provide sterile communication with the atmosphere for venting (see column 2, FIGS 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a detachable venting cover as disclosed by Yokoyama to the infusion connector suggested by the prior art in order to provide a sterile vent, as taught by Yokoyama.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, further in view of US 4,623,343 to Thompson.

In the specification and figures, Wessman and Loo suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of internal threads on the connector to attach the giving set cap to drip chamber 12. Threaded

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connections between fluid passageways are well known in the art of fluid infusion, as demonstrated by Thompson, who discloses a threaded connection 54 between fluid syringe 12 and connector 12 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a threaded connection between the subsidiary channel inlet and the vent cap, since such connections are well known in the art.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al, further in view of US 4,687,473 to Raines.

In the specification and figures, Wessman and Loo disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of a line attached to the drip chamber. It is well known in the art of infusion to attach an infusion line to drip chambers for patient infusion, as illustrated by Raines (see drip chamber 27 attached to infusion tubing line 29 in FIGS 1-2). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add an infusion line as disclosed by Raines to the giving set cap or connector with drip chamber as suggested by the prior art in order to allow for patient infusion.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al in view of US 3,662,752 to Yokoyama, further in view of US 4,623,343 to Thompson.

In the specification and figures, Wessman, Loo, and Yokoyama suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception

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of threads to attach the vent cap to the subsidiary channel inlet. Threaded connections between fluid passageways are well known in the art of fluid infusion, as demonstrated by Thompson, who discloses a threaded connection 54 between fluid syringe 12 and connector 12 (see FIG 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide a threaded connection between the subsidiary channel inlet and the vent cap, since such connections are well known in the art.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,409,708 to Wessman in view of US 5,041,087 to Loo et al in view of US 3,662,752 to Yokoyama, further in view of US 4,687,473 to Raines.

In the specification and figures, Wessman, Loo, and Yokoyama suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of a vent cap attached to the device by means of a hinge. Raines discloses a fluid infusion kit with a port 19 and cap 21 attached to the housing with a tether or hinge 38 to prevent loss of the cap (see FIGS 2, 2A). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a tether or hinge as disclosed by Raines to the infusion connector with vent cap as suggested by the prior art in order to prevent loss of the cap.

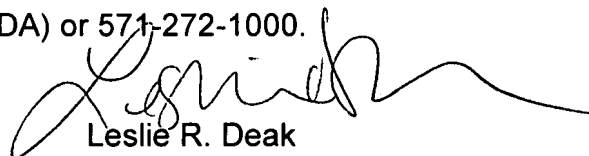


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
18 July 2007